

Message

From: Striegel, Wiebke [Striegel.Wiebke@epa.gov]
Sent: 2/25/2020 1:03:28 PM
To: Kirk, Cassandra [kirk.cassandra@epa.gov]
Subject: RE: Oxitec HH & PC DERs

Sounds good, I'm in the office today, too!

From: Kirk, Cassandra <kirk.cassandra@epa.gov>
Sent: Tuesday, February 25, 2020 8:02 AM
To: Striegel, Wiebke <Striegel.Wiebke@epa.gov>
Subject: RE: Oxitec HH & PC DERs

Chris was supposed to review the eco ones but no one was assigned for the tetracycline or arbo studies. I'm coming in late today but let's chat briefly about Oxitec some time today.

Cassie

From: Striegel, Wiebke <Striegel.Wiebke@epa.gov>
Sent: Tuesday, February 25, 2020 8:00 AM
To: Kirk, Cassandra <kirk.cassandra@epa.gov>
Subject: RE: Oxitec HH & PC DERs

Hello Cassie,

Does this also mean that no secondary reviewer has been assigned to these?

Wiebke

From: Kirk, Cassandra <kirk.cassandra@epa.gov>
Sent: Monday, February 24, 2020 12:40 PM
To: Striegel, Wiebke <Striegel.Wiebke@epa.gov>; Kough, John <Kough.John@epa.gov>; Wozniak, Chris <wozniak.chris@epa.gov>
Subject: RE: Oxitec HH & PC DERs

Thanks for the update!

The total studies that I have still requiring secondary review are as follows:

- Acute invert- tox (50889407)
- Wild mammal- waiver (50889422)
- ESA- (50889414)
- Arbovirus testing
- Tetracycline (50889415)

Cassie

From: Striegel, Wiebke <Striegel.Wiebke@epa.gov>
Sent: Monday, February 24, 2020 12:20 PM
To: Kough, John <Kough.John@epa.gov>; Wozniak, Chris <wozniak.chris@epa.gov>; Kirk, Cassandra

<kirk.cassandra@epa.gov>

Subject: Oxitec HH & PC DERs

Hello everyone,

Thanks again for meeting this morning, it was really helpful to work through the scheduling and some of the issues with the application. Cassie, I'll talk to you tomorrow to get you up to speed!

Here is what came out of my meeting with Mike this morning:

- The current deadline for the secondaries is **March 12**, which would give John 7 work-days to review the DERs and the risk assessment.
- Mike is going to talk about John's schedule for that week with (I assume) Shannon and Bob, to see if John's schedule can be freed up.
- Mike is going to contact Chris to see which DERs he may be able to secondary (I told him about the arbovirus testing and the product characterization may be another one). He also suggested Mark as a potential secondary for the acute tox waivers.

Below is a table of the Human Health & PC related DERs that will need to be secondaried. It is my understanding that Chris is already the secondary on the penetrance data (the field data from Brazil) as well as the vector competence memo that we just got back from CDC (is that correct?).

Let's keep checking in with each other over the next two weeks to have a chance to meet the deadline.

Complete SOPs	50889427	1	Chris
Manufacturing Process	50889424	1	Chris
Product characterization	50889401	1	Wiebke
Acute Oral - <i>waiver</i>	50889402	1	Wiebke
Acute Inhalation - <i>waiver</i>	50889403		
Primary Eye - <i>waiver</i>	50889404		
Primary Dermal - <i>waiver</i>	50889405		
Hypersensitivity	50889406		
Insecticide susceptibility	50698718	1	Wiebke
Insecticide susceptibility (suppl.)	50889418*		
kdr mutation	50698718		
Protein qWestern	50889419	1	Wiebke
Bioinformatics toxicity/ allergenicity	50889420	1	Wiebke
Protein degradation study and bioinf.	50889421	1	Wiebke
Arbovirus test in original SOPs	50698723	1	Cassie
Arbovirus Testing	50889425		

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